

# Worldwide Infrastructure for Facilitating Traceability, Comparability and Recognition of Chemical Measurement Results

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- Climate change and environmental control
- Food safety and the Codex Alimentarius
- Anti-doping, Forensics, Pharmaceuticals
- New developments, new fields, new networks
- What to do, how to organize



# The need for new objectives in Metrology

- Industrial production (**parts** produced at another time somewhere else on the globe **must fit**)
- Trade (fair trade, internal markets, trade agreements)
- Accreditation agreements
- Society
  - environment
  - health care
  - food
  - drugs and pharmaceuticals
  - biologicals
- Regulators
- Forensics
- Security

# The need for new objectives in Metrology

- Technical Barriers to Trade (WTO TBT)
- Sanitary and Phyto-Sanitary measures (SPS)
- Regulations (EU Directives, US legislation, national regulations)
- Codex Alimentarius, Pharmacopeia, ISO, sector specific standardization bodies
- Accreditation (ILAC Arrangements, e.g. based on ISO 17025, 15189, 15195, WADA, etc.)

# Why is there a broader need?

- Environment : clean air, soil, water  
: trading CO2 shares
- Health care : proper treatment of patients  
: trade in diagnostic markers,  
pharmaceuticals, testing & insurance costs
- Food analysis : food safety testing  
: food trade
- Anti-doping : fair sports, healthy sportsmen  
: sports income
- Crucial issues for society and legislators with big economic, trading and industrial consequences

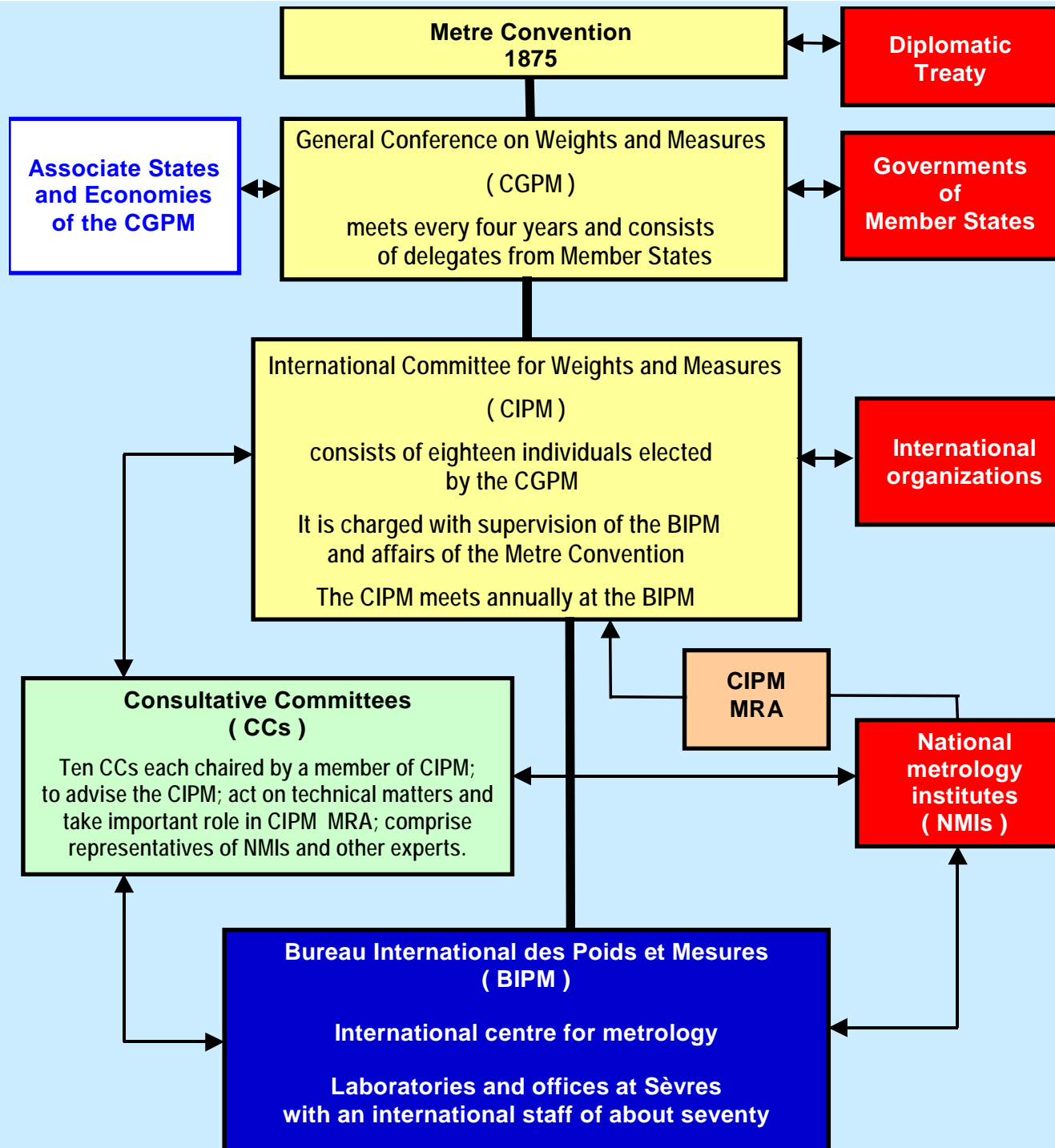
# New approaches required

- Not well defined measurands, e.g. undefined molecules in an undefined matrix environment
- Method dependent results
- Bio activity, e.g. to be expressed in katal
- Non SI traceable results
- New quantities and units?

# Establishing worldwide comparability through traceability

- **Inter-Governmental Treaty** of the **"Metre Convention"**, established in 1875
- Member States (51) and Associate countries and economies (30) (October 2005)
- 10 Consultative Committees
- International Bureau (BIPM) in Sèvres, France
- Coordinating and representing the National Metrology Institutes (NMI's) globally





# The CIPM Consultative Committees and the BIPM

## ➤ BIPM

- Primary and transfer standards
- Calibrations, comparisons, coordination
- Liaison with inter-governmental and international organisations
- CIPM MRA

## ➤ Consultative Committee on Metrology in Chemistry

- Development and validation of primary and other methods
- Organisation of comparisons (studies and key comparisons)
- Review of calibration and measurement capabilities
- Workshops, liaison with stakeholder organisations

# The CIPM Mutual Recognition Arrangement

- Mutual recognition of national measurement standards and of calibration and measurement certificates issued by NMI's (and other designated institutes)
- Now signed by a large and increasing number of NMI's and other designated institutes (some 170), acting as NMI's for certain quantities and measurement ranges, of about 75 Member States and Associate Economies and 2 international organizations (IAEA and EC (IRMM and JRC-Ispra)). (See **Appendix A**)

# The CIPM Mutual Recognition Arrangement

- Based on results of key-, supplementary- and bilateral comparisons (**Appendix B**)
- Quality system in place in conformity with ISO/IEC 17025 and ISO Guide 34
- Quality system assessment by RMO review, accreditation and/or on-site peer review
- Regional and inter-regional review of claimed calibration and measurement capabilities

## Appendix C of the CIPM MRA

- Published are the calibration and measurement services of the (designated) NMI's and other institutes, which are normally delivered to the customers
  - \* Analysing/measurement/calibration capabilities and/or
  - \* CRM's delivered/sold to customers
- Key Comparison Data Base – KCDB on [www.bipm.org/kcdb](http://www.bipm.org/kcdb)

# Appendix C chemistry CMC template April 2001

ry	Designated Service Provider	NMI Service Identifier	Measurement Service Category No.	Measurement Service Sub-Category No.	Measurement Service Category	Matrix	Measurand			
							Analyte Group Identifier	Analyte or component	CAS Number	Quantity
y A	NMI A	1	4	4.2	Environmental	nitrogen		carbon monoxide	630-08-0	Amount-of-substance fraction
y A	NMI A	2	4	4.2	Environmental	nitrogen		nitrogen monoxide	10102-43-9	Amount-of-substance fraction
y A	NMI A	3	4	4.2	Environmental	nitrogen		nitrogen monoxide	10102-43-9	Amount-of-substance fraction
y A	NMI A	4	4	4.2	Environmental	nitrogen		ammonia	7664-41-7	Amount-of-substance fraction
y A	NMI A	5	4	4.4	Forensic	synthetic air		ethanol	64-17-5	Amount-of-substance fraction

Dissemination Range of Measurement Capability			Range of Expanded Uncertainties for Measurement Capability						Range of Certified Values in Reference Materials			Range of Expanded Uncertainties for Certified Value					
From	To	Unit	From	To	Unit	Coverage factor	Level of confidence	Is the expanded uncertainty a relative one?	From	To	Unit	From	To	Unit	Coverage factor	Level of confidence	Is the expanded uncertainty a relative one?
10	100	µmol/mol	0.4	0.3	%	2	95%	Yes	10	100	µmol/mol	0.4	0.3	%	2	95%	Yes
100	1000	nmol/mol	3	2	%	2	95%	Yes	100	1000	nmol/mol	3	2	%	2	95%	Yes
1	10	µmol/mol	2	1	%	2	95%	Yes	1	10	µmol/mol	2	1	%	2	95%	Yes
10	100	µmol/mol	10	5	%	2	95%	Yes	10	100	µmol/mol	10	5	%	2	95%	Yes
100	1600	µmol/mol	0.5	0.5	%	2	95%	Yes	100	500	µmol/mol	0.5	0.5	%	2	95%	Yes

Mechanism(s) for Meas Service Delivery	Source of Traceability	Measurement Technique(s) Used	Link(s) to Appendix B (Key Comp. Name)	Comment(s) of Service Provider	RMO Services Administration (for RMO use only)		Comments
					Review Code / Status	Review Comments	
PRGM, SGS & calibration	NMI A	NDIR	COQM-K1 a Euromet 313	Static gravimetric preparation: Analysis against primary binary standards			Uncertain
SGS & calibration	NMI A	Chemiluminescence	Euromet 430	Static gravimetric preparation: Analysis against primary binary standards			Uncertain
PRGM, SGS & calibration	NMI A	Chemiluminescence	Euromet 430	Static gravimetric preparation: Analysis against primary binary standards			Uncertain
SGS & calibration	NMI A	Chemiluminescence & FTIR		Static gravimetric preparation: Analysis against primary binary standards			Uncertain
PRGM, SGS & calibration	NMI A	Flame Ionisation	COQM-K4	Static gravimetric preparation: Analysis against primary binary standards			Uncertain

## Consultative Committee for Amount of Substance – CCQM - Metrology in Chemistry

- Established by the CIPM in 1993
- 35 member and observer organizations
- Yearly meetings of CCQM plenary, attended by some 60 representatives
- 7 working groups, meeting twice a year and attended by some 170 experts from NMI's and other expert institutes

# Consultative Committee for Amount of Substance – CCQM - Metrology in Chemistry

## Aim

- To establish worldwide comparability, through
- Traceability to SI, or if not (yet) possible to other internationally agreed references, by
- Development of primary and other methods, databases and
- Primary (pure) reference materials and
- Validation of traceable methods
- To contribute to the establishment of a globally recognized system of national measurement standards and facilities and the implementation of the CIPM MRA
- To advise the CIPM and the BIPM on metrology in chemistry

# CCQM

## CCQM Working Groups

- Key Comparisons and CMC Quality  
NRC-INMS
- Organic Analysis  
NIST
- Inorganic Analysis  
LGC
- Gas Analysis  
NMI
- Electro-chemical Analysis  
SMU
- Surface Analysis  
BAM
- Bio-Analysis  
LGC

# Establishing Comparability through Traceability

- Metrological traceability
  - ✓ Traceability to SI or if not yet possible to an other internationally agreed reference
  - ✓ Globally reliable and comparable measurement values with a stated uncertainty, traceable to long term stable measurement standards (Trueness)

# CCQM Metrology in Chemistry

## Areas defined in overall framework (1)

- Health (clinical diagnostic markers)
- Food (pesticides, toxins, drinking water)
- Environment (water, air, global warming, contaminants in soil)
- Advanced materials (semiconductors, alloys, plastics)
- Commodities (oil, cement, precious metals, alcohol content)

# CCQM Metrology in Chemistry

## Areas defined in overall framework (2)

- Forensics (drugs, explosives, breath analysis, DNA)
- Pharmaceuticals
- Bio-technology (GMO's, DNA profiling, diagnostics)
- General analytical applications (purity, pH, isotopic standards)
- Surface analysis

# CCQM WG on Organic Analysis

- P,p'DDT in fish oil
- LSD in human urine
- Cholesterol in human serum
- Glucose and creatinine in human serum
- PCB's in sediment
- Organic purity assessment series
- Ethanol in aqueous matrix (forensic level)
- Organic calibration solutions (PCB, PAH, pesticides, etc.)
- Drugs of abuse in urine

# CCQM WG on Inorganic Analysis

- Mono-elemental solutions
- Pb and Cd in sediment
- Zn and Cd in rice ; Pb in wine
- Ca in serum
- As in fish or shellfish
- Metals food digest
- S in fuel
- Minor elements in steel
- Boron in Si
- Purity of HCl

# CCQM WG on Gas Analysis

- CO, CO<sub>2</sub>, NO, SO<sub>2</sub>, H<sub>2</sub>S, NH<sub>3</sub>, HCl in nitrogen
- Natural gas
- Automotive emission gases
- Ethanol in air
- BTX in nitrogen
- VOC's at workplace and ambient levels
- Purity analysis o-xylene
- Ozone and greenhouse gases
- CFC's and SF<sub>6</sub> at emission levels

# CCQM WG on Electrochemical Analysis

- pH
- Electrolytic conductivity
- Coulometry

# CCQM WG on Surface Analysis

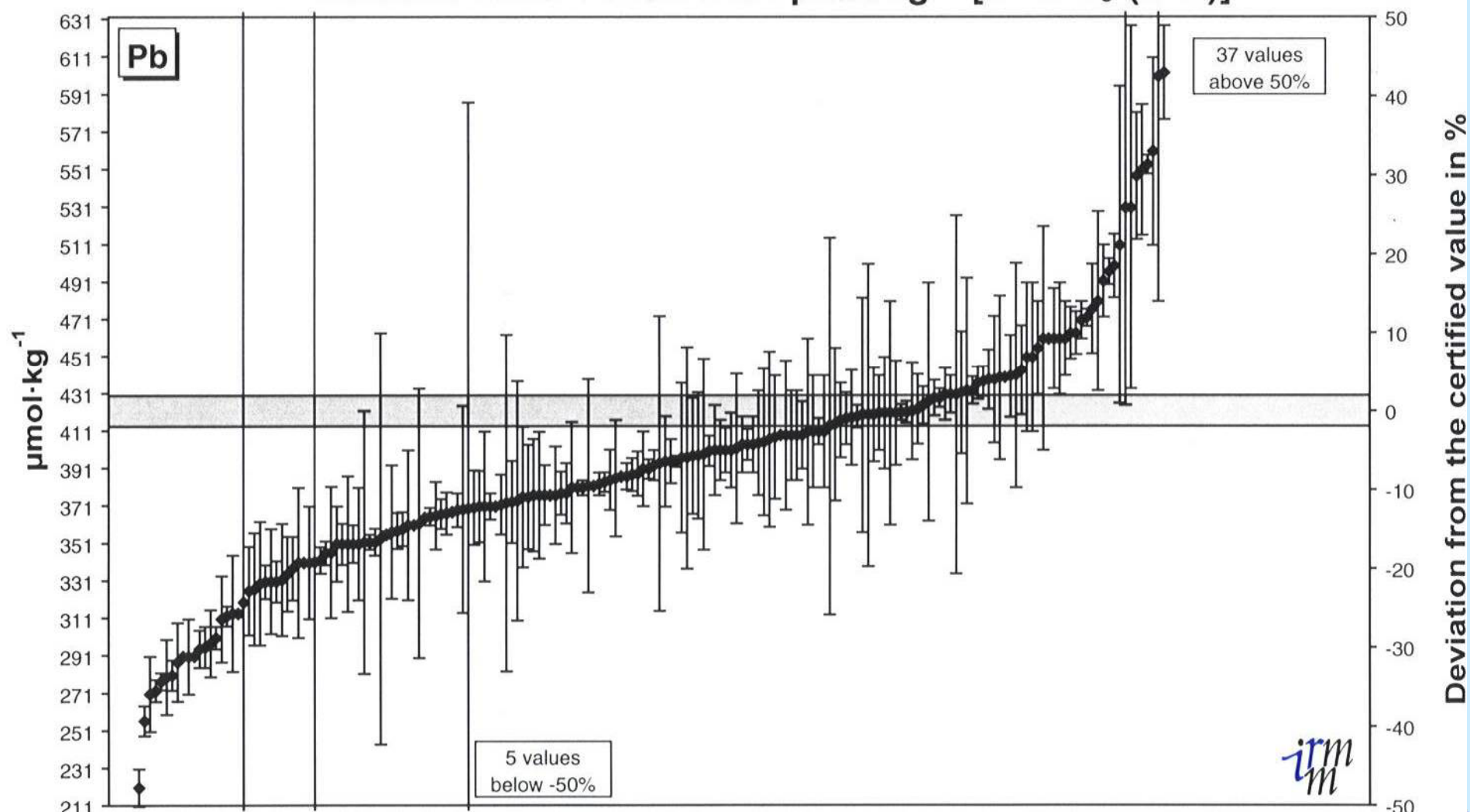
- Development towards Surface and Micro/Nano Analysis, for example:
- Dopant distribution in Si
- Fe-Ni and Co-Pt alloy thin films composition
- Coatings
- Surface layers, contaminations
- Polymer surfaces
- Thin film multilayers systems
- SiO<sub>2</sub> oxide on Si wafers

# CCQM WG on Bio Analysis

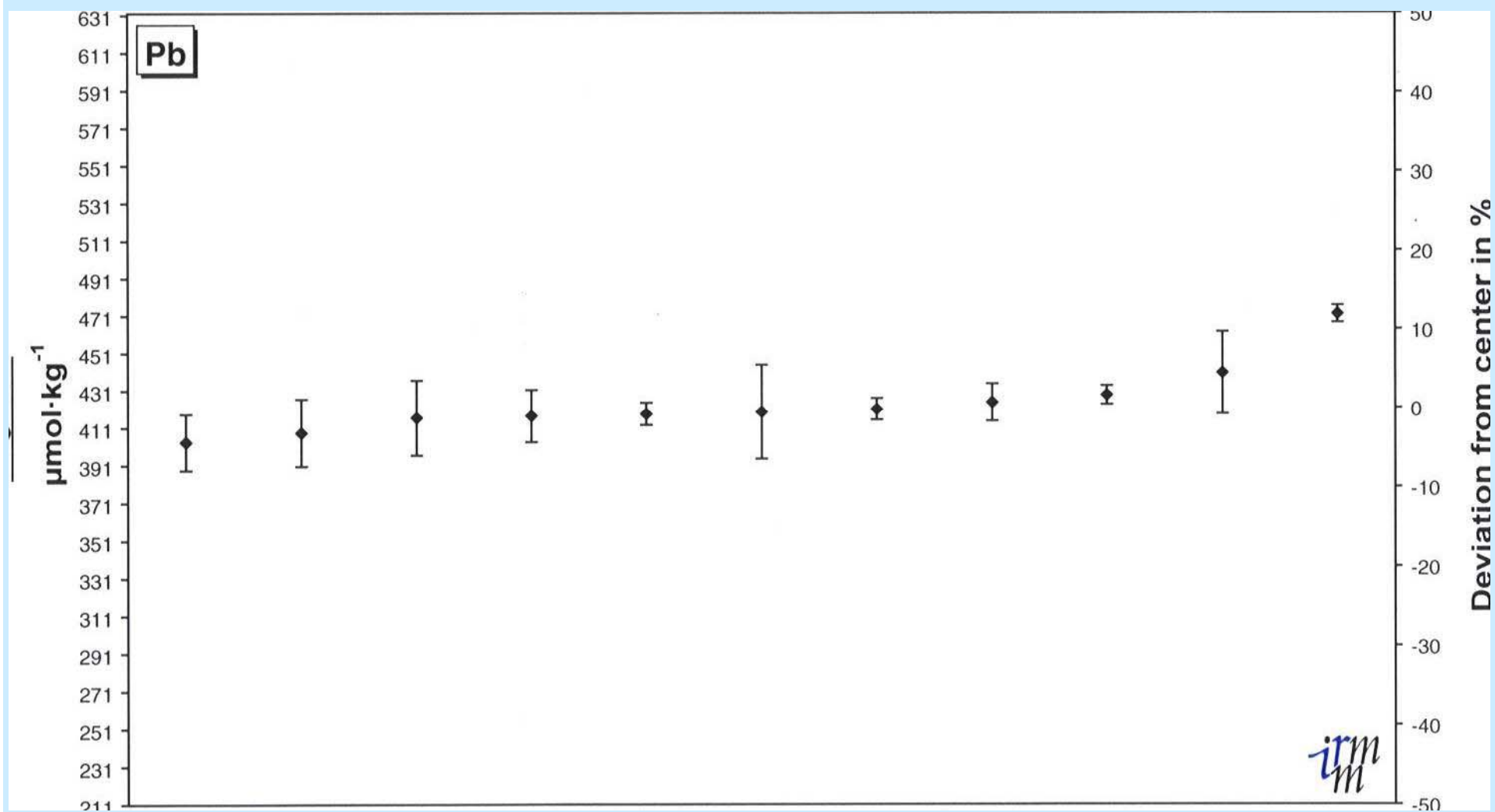
- PCR quantitation study
- Fluorescent dyes spectral correction studies
- Comparability study of results obtained by the use of a DNA profiling technique
- Circular dichroism pilot study
- DNA primary quantitation reference method
- Peptide/protein quantitation in proteomics
- Biomolecular measurements
  - proteomics (proteins)
  - genomics (DNA, RNA, GMO's)
  - cells (cell stams)

# IMEP- 14 : Trace elements in sediment

Certified value :  $421.1 \pm 8.4 \mu\text{mol}\cdot\text{kg}^{-1}$  [ $U=k\cdot u_c$  ( $k=2$ )]



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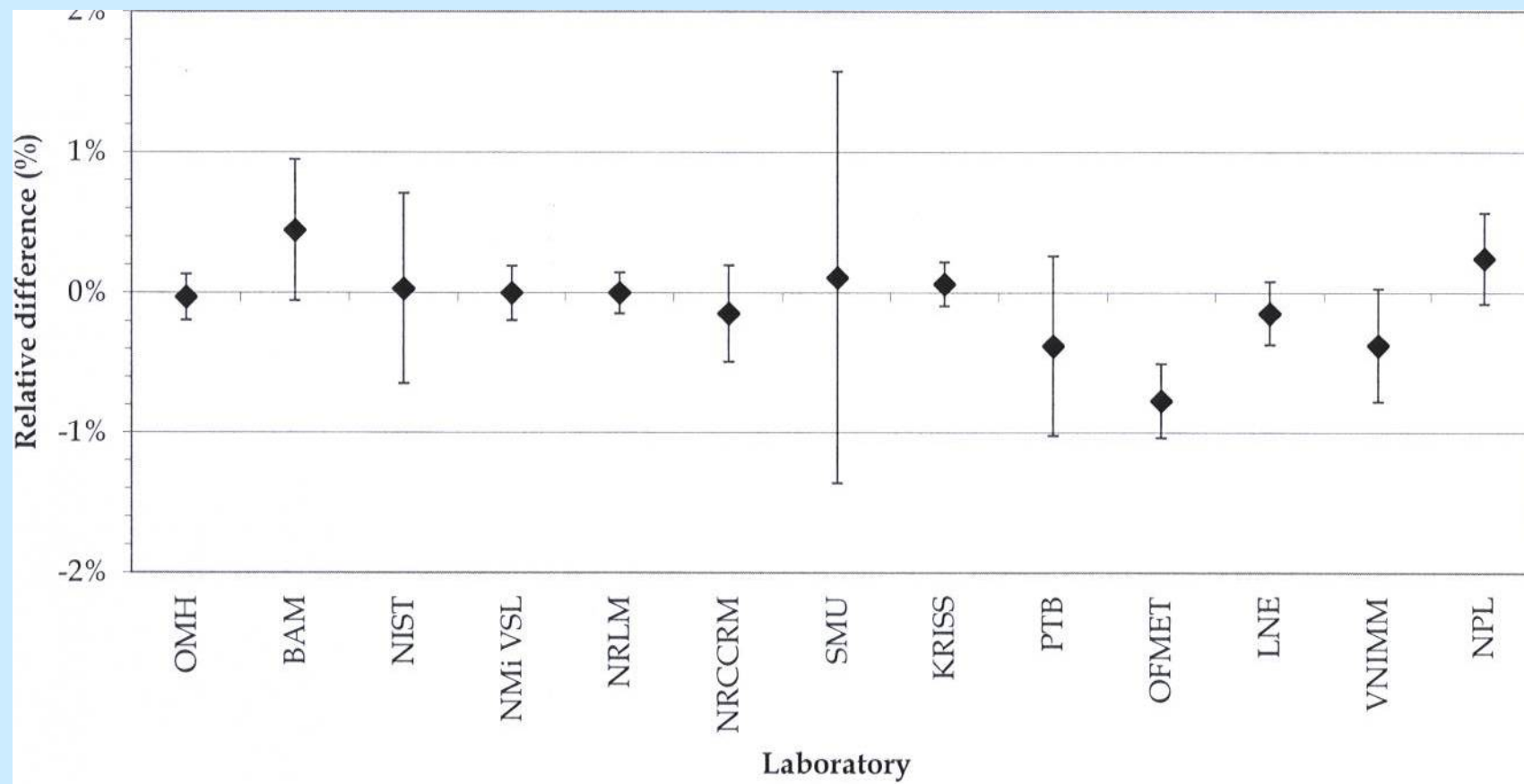


Figure 4: Results for  $C_3H_8$

Arsenic Concentration (mmol/kg)

# CCQM-P11

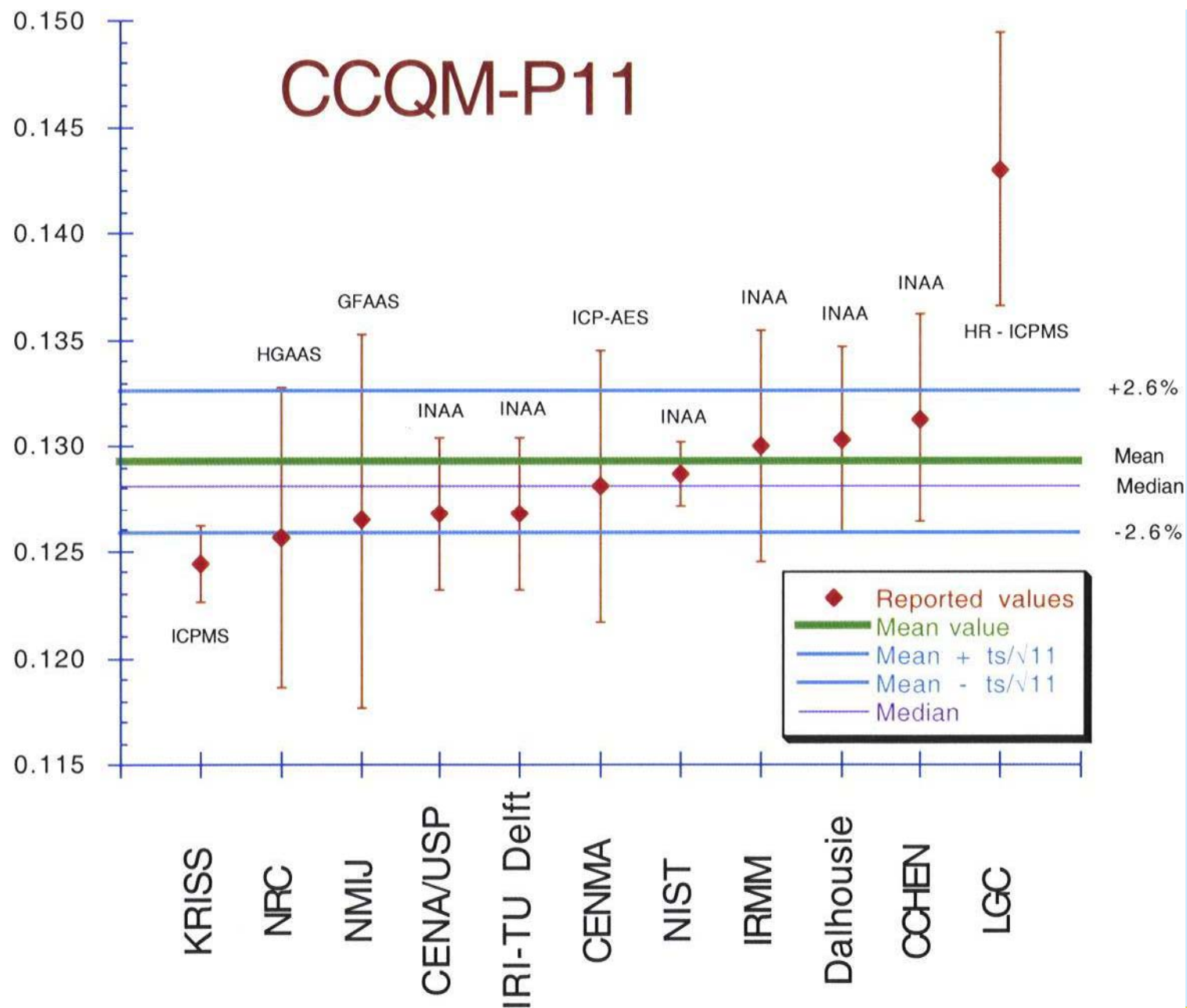
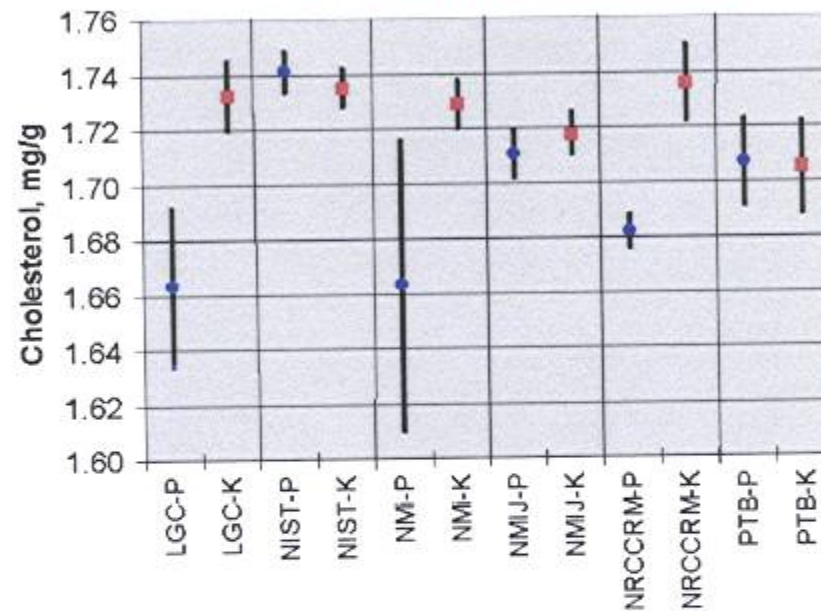


Figure 2. Comparison of Results from the Key Comparison and the Pilot Study on the Same Material

**CCQM – Comparison of Results for Cholesterol in Serum**  
**in 1999 Pilot Study • and in 2000 Key Comparison ■ (CCQM-K6)**

mean  $\pm$  U:  $1.700 \pm 0.029$  mg/g (Pilot: CCQM-P6 Matl A<sub>0</sub>)  
 $1.726 \pm 0.013$  mg/g (Key: CCQM-K6 Matl B)



# Why to bother?

## Health care (treatment, losses)

- Often no traceability to SI
- Often no long term stable references
- Often no comparability between measurement systems produced by different manufacturers
- Repeated measurements cost a fortune
- Wrong measurement results
  - Wrong medical treatment decisions

## Economic and Social Impact

- Mayo Clinic and NIST studies show that 3% measurement error in cholesterol measurements lead to 5% false diagnoses, leading to unnecessary treatment or dramatic non-treatment
- Same applies for measurement errors in Cardiac Troponin-I analysis, a heart attack marker
- Avoiding unnecessary measurements could potentially save the US 10 to 30 billion US\$ p.a.
- In Germany savings would be  $> 1.5$  billion €

# Joint Committee on Traceability in Laboratory Medicine - JCTLM

- Triggered by the need for reliable, comparable and traceable measurements in laboratory medicine
- Rapid developments in science and new technologies
- Implementation of quality systems (ISO/IEC 17025, ISO 15189 and ISO 15195)
- Need to reduce costs
- Legislation – EU directive on In-Vitro Diagnostics requiring traceability

# JCTLM

- Implementation of
  - EC-IVD Directive (98/79/EC)
- EC-IVD Directive, Annex I, Essential requirements A.3
- '...The traceability of values assigned to calibrators and/or control materials must be assured through available reference measurement procedures and/or available reference materials of a higher order.'

# Joint Committee on Traceability in Laboratory Medicine - JCTLM

## Principal promoters

- CIPM/BIPM
- IFCC
- ILAC

## Supported by

- WHO
- Other stakeholders

# Joint Committee on Traceability in Laboratory Medicine - JCTLM

## Other stakeholders

- Regulators (FDA, EC, Japan)
- CRM producers (NIST, IRMM, a.o.)
- Reference laboratories (CDC, DGKS, etc.)
- PT and QA organisations (CAP, EQA, etc)
- Written Standards (NCCLS, JCCLS, ISO)
- IVD industry (ADVAMED, EDMA, JARC)

# Organization Structure

- **JCTLM Executive**
  - Chairman - IFCC : Prof J H H Thijssen
  - Secretariat - BIPM
  - Executive Secretary: Dr R I Wielgosz
  - IFCC, ILAC, BIPM/CIPM and JCTLM WG Chairmen
- **Working Groups:**
  - WG 1: Reference Materials and Reference Procedures
  - WG 2: Reference Measurement Laboratories

# JCTLM Highest Priority Analyte Categories & Review Team Leaders

## Analyte Category

## Review Team Leaders

*(With representative examples)*

### Coagulation Factors

**Elaine Gray, NIBSC**

*WHO 2nd International Standard for Antithrombin Plasma, Human*

*WHO 1st International Standard for Beta Thromboglobulin Human purified*

### Drugs [therapeutic and “of abuse”] **Andre Henrion, PTB**

*Digoxin/ Digitoxin*

*Theophylline*

*Cocaine*

*THC-COOH*

### Electrolytes

**Richard Miller, Dade Behring**

*Calcium*

*Potassium*

*Sodium*

### Enzymes

**Mauro Panteghini, Azienda Ospedaliera “Spedali Civili”**

*AMYLASE, CK, GGT*

# JCTLM Highest Priority Analyte Categories & Review Team Chairs – cont'd

## Analyte Category

## Review Team Chair

*(With representative examples)*

### Nucleic Acids

Helen Parkes, LGC

*Hepatitis A virus RNA*

*Hepatitis B virus DNA*

### Metabolites and Substrates

Michael Welch, NIST

*Cholesterol*

*Creatinine*

*Glucose*

### Non-Peptide Hormones

Heinz Schimmel, IRMM

*Cortisol*

*Estradiol-17 $\beta$*

*Thyroxine*

### Proteins

David Sogin, Abbott Laboratories

*Albumin*

*Troponin-I*

*PSA*

# JCTLM Highest Priority Analyte Categories & Review Team Chairs – cont'd

## Analyte Category

*(With representative examples)*

**Blood gases**

## Review Team Chair

**Susan Blonshine, NIBSC**

**Blood grouping**

**Sue Thorpe, NIBSC**

**Microbial serology**

**Morag Ferguson, NIBSC**

*Hepatitis B surface antigen (HBsAg)*

*Antibodies to hepatitis A virus*

*Antibodies to toxoplasma*

**Vitamins and Micronutrients**

**Katherine sharpless, NIST**

*Retinol (Vitamin A)*

*Alpha Tocopherol (Vitamin E)*

*beta Carotene*

**Non-electrolyte metals**

**Lee Yu, NIST**

*Arsenic*

*Cadmium*

*Lead*



# Climate change and air quality

- WMO Global Atmospheric Watch
  - CIPM/BIPM – WMO MoU
  - BIPM Ozone measurements
- Trading CO<sub>2</sub> shares
- EU air quality requirements
- Exhaust gases
- CCQM WG on Gas Analysis extensive programme

# Water and soil quality and pollution

- Ocean water, border crossing rivers, surface water
- Soil and sediment
  - heavy metals in water, soil and sediment
  - PCBs, tributyltin, etc.
- CCQM WGs on Inorganic Analysis and Organic Analysis extensive programme

# Why to bother?

## Food scandals

- Growth hormones in beef
- Dioxine in milk
- Heavy elements in rice and wine
- Glycol in wine, diesel oil in olive oil
- Salmonella in eggs
- BSE in beef
- Toxic residues in fish
- GMO's
- Dietary supplements

# Trade and food safety

- Metrology in support of export, often food products
- For example poor metrological, testing and quality infrastructure led in 1999 to the EU ban of Nile perch, creating a loss of 100 million US dollars per annum and an increase in unemployment of 150 000 jobs
- Metrology to protect own society against dangerous, unsafe and toxic products, including imported products
- E.g., imported fertilizers and agricultural or animal products containing toxic elements or dangerous diseases (grains, honey, fruits, meat, fish, wine, etc., etc.)

# Food Safety from FARM to FORK

- Soil, water, air quality
- Treatment of seeds and plants
- Fertilizers
- Animal feed (natural and industrial)
- Treatment of animals (treatment for sickness, hormones)
- Industrial food processing
- Storage, transport, sales, delivery conditions

Food is one of the biggest business and safety issues in the world

# Protect the people, animals, our environment

- National regulations
- Regional regulations, e.g. EU Directives
- Harmonization and recommendations by the Codex Alimentarius Committee (FAO / WHO)
- WTO Technical Barriers to Trade committee aiming to take away TBT (avoiding market distortion)
- Sanitary and Phyto-Sanitary requirements (consumer safety)

# Establishing Metrological Traceability

## Driving forces

- Trade specifications
- Compliance with regulations (a.o. food safety)
- Labeling (vitamins, amino and sorbic acids, fat, GMO, caffeine, etc.)
- Tariff classification (butter fat, sugars, caffeine, fat in milk, protein in meat)
- Avoidance of market distortions in a single market

# Food chain and Animal and Plant health control

## Regulations in the EU

- EU Council Dir.93/99/EEC Official Control of Food Stuffs
- EU Council Dir.96/23/EC Performance of analytical methods and interpretation of results
- EU Commission Dec. 98/179/EC Residues in live animals and animal products
- EU Commission Dec. 2002/657/EC Performance criteria and procedures (criteria approach)
- And more to come

# EU Directives

## Legislation includes:

- Aflatoxins, ochratoxins
- Patulin, dioxins, PCBs
- Pesticides
- Pb, Cd, Hg
- Inorganic tin in food
- Cocoa, chocolate products
- Novel foods, GMOs
- Migration of Pb, Cd from ceramic ware into food
- Labeling, infant formula. Commodities
- Requirements for analysis by laboratories engaged in official control

# Food chain and Animal and Plant health control

## US Regulations

- US Infant Formula Act, 1980
- US Nutritional Labelling and Education Act, 1990
- US Dietary Supplement Health and Education Act, 1994
- Contaminants in seafood (PCBs, MeHg in fish, oyster, mussel)

# US Regulations

## **Legislation includes:**

- Total fat
- Saturated fat
- Cholesterol
- Sodium
- Carbohydrates
- Dietary fiber
- Sugars
- Protein
- Vitamin
- Calcium, iron

# Dietary Supplement Standard Reference Materials (SRMs)

## Priorities

- Current NIST priorities
  - Ephedra
  - *Ginkgo biloba*
  - Saw Palmetto
  - *Citrus aurantium* (bitter orange)(synephrine)
  - St. John's Wort
  - Green Tea
  - $\beta$ -Carotene (carotenoids in oil matrix)
  - Vitamin E (tocopherols)
- Other priorities
  - Panax ginsengs (Asian/American) (NRC Canada)
  - Eleuthero/Siberian ginseng (NRC Canada)

# CCQM Workshop on Comparability and Traceability in Food Analysis (November 2003)

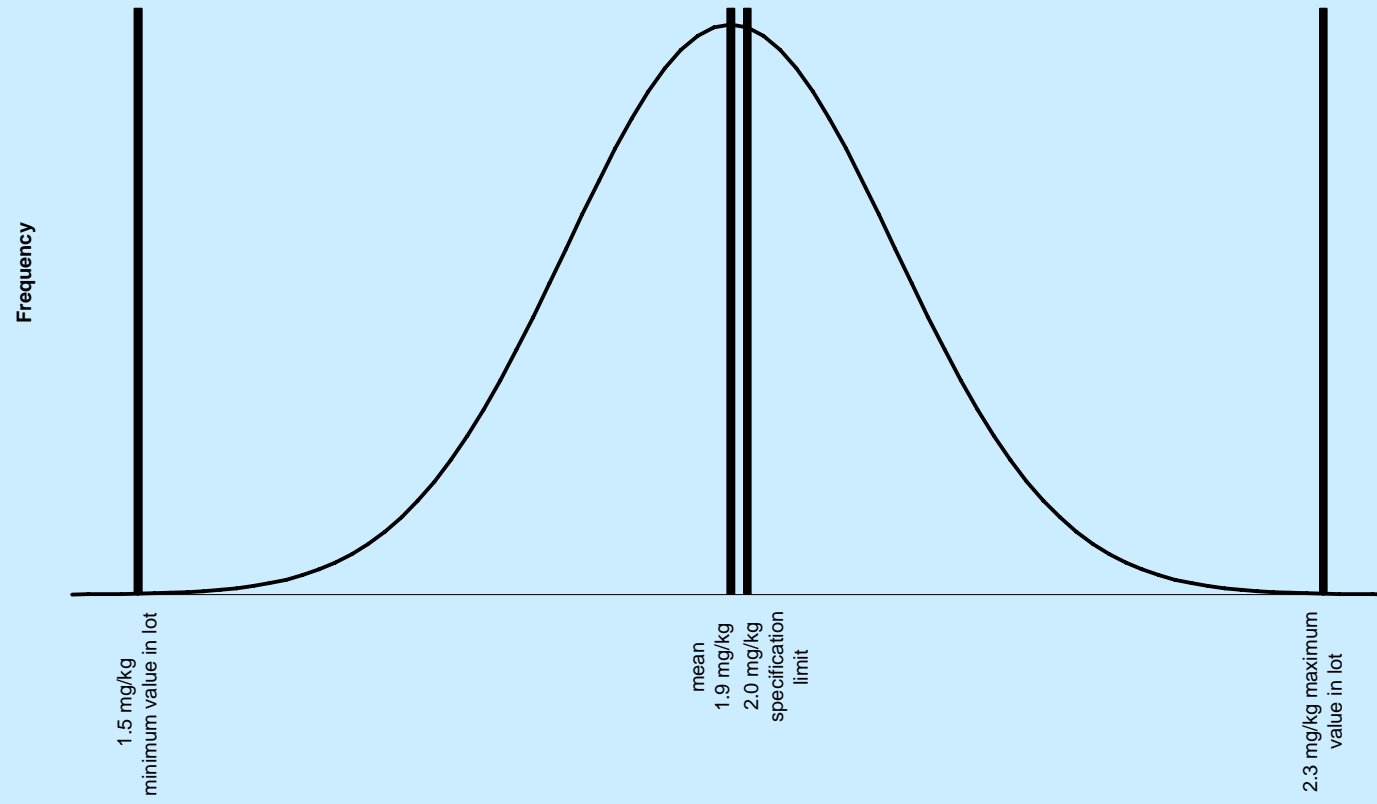
## Stakeholders

- BIPM and NMI's
- Codex Alimentarius Commission and IAM
- EURACHEM/CITAC
- Regulators (Australia, EU, Japan, USA)
- CRM producers (IRMM, NIST, AGAL)
- Industry
- Food testing laboratories
- EU Reference laboratories
- Sectoral organizations (IOVV and IOOC)
- Accreditation and Standardization

# CCQM Focus Group Meeting on Reference Measurement Systems for Food Analysis, (September 2004)

## Participants

- BIPM/CCQM and NMI's
- Codex Alimentarius Commission and IAM
- International Dairy Federation
- CRM producers (IRMM, NIST)
- EU Reference laboratories
- Proficiency Testing providers (EU, IDF, FAPAS, a.o.)



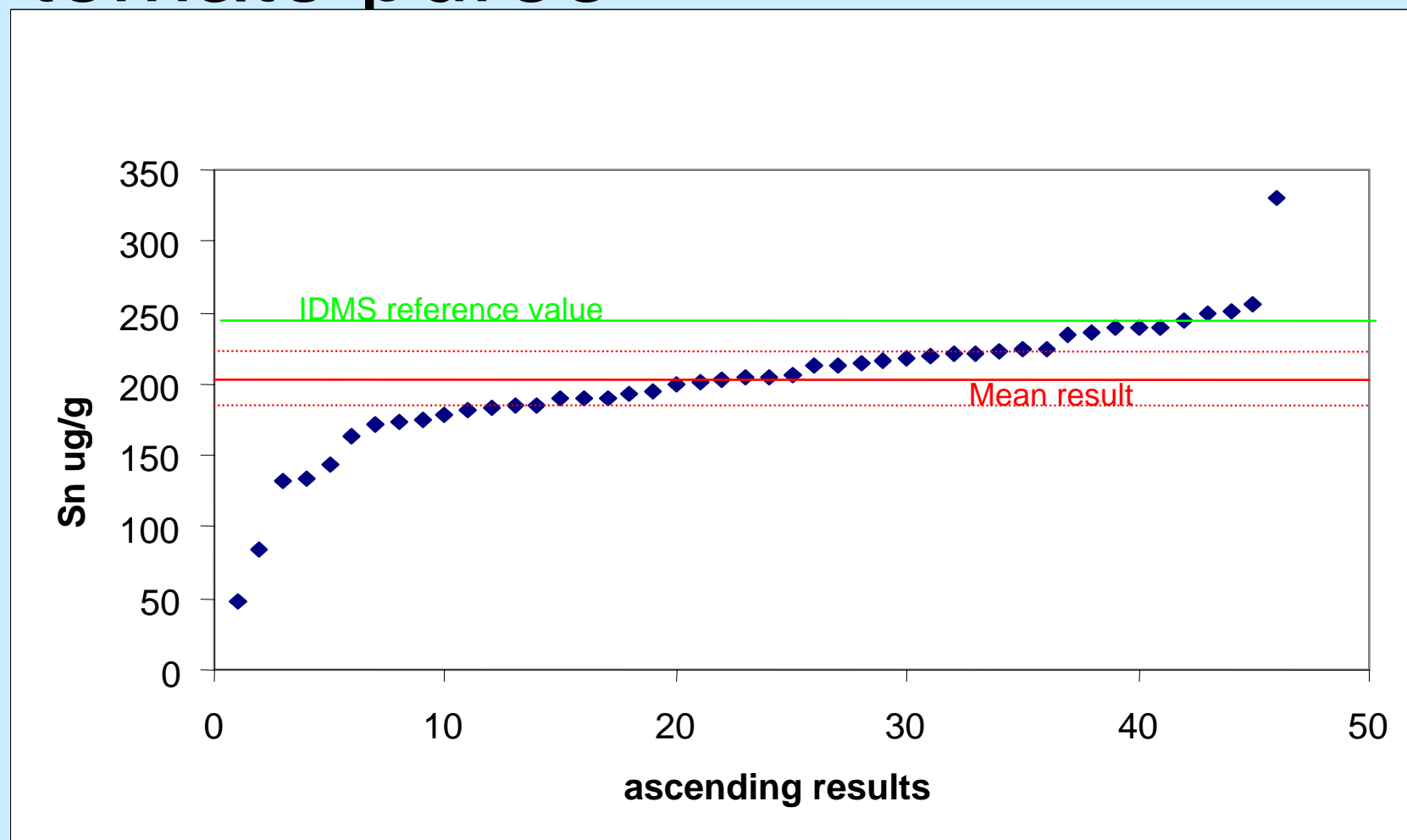
# FAPAS experience, January 2004

Food Analysis Performance Assessment Scheme (UK  
Ministry of Agriculture, Fisheries and Food)

## Tin in tomato puree

- If the reference value for tin, obtained by ICP-IDMS, was taken as assigned value: 60% of participants obtained satisfactory z-score
- If consensus value had been taken 72% of participants obtained satisfactory z-score

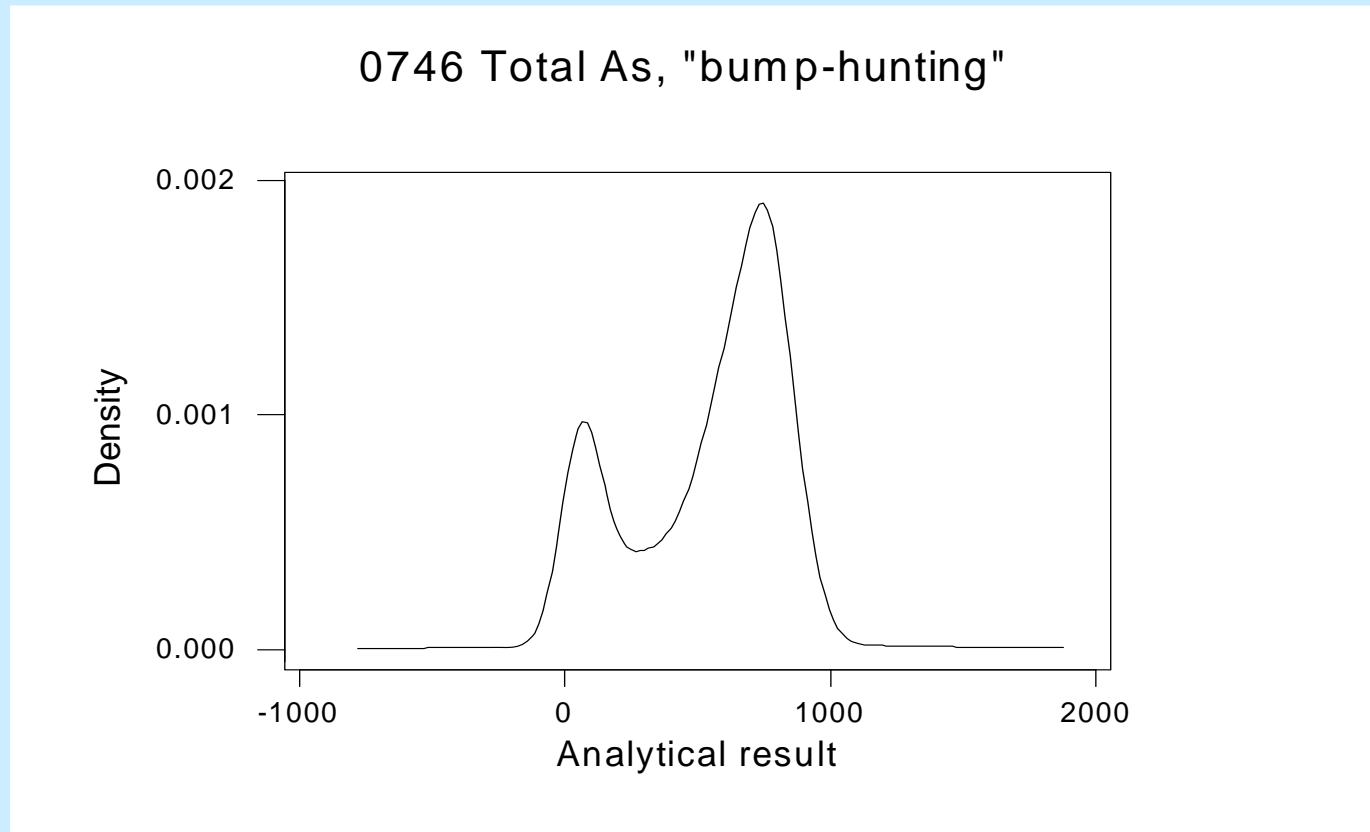
# FAPAS Round 0738: Sn in tomato puree



# Change in Sn performance using reference instead of consensus value

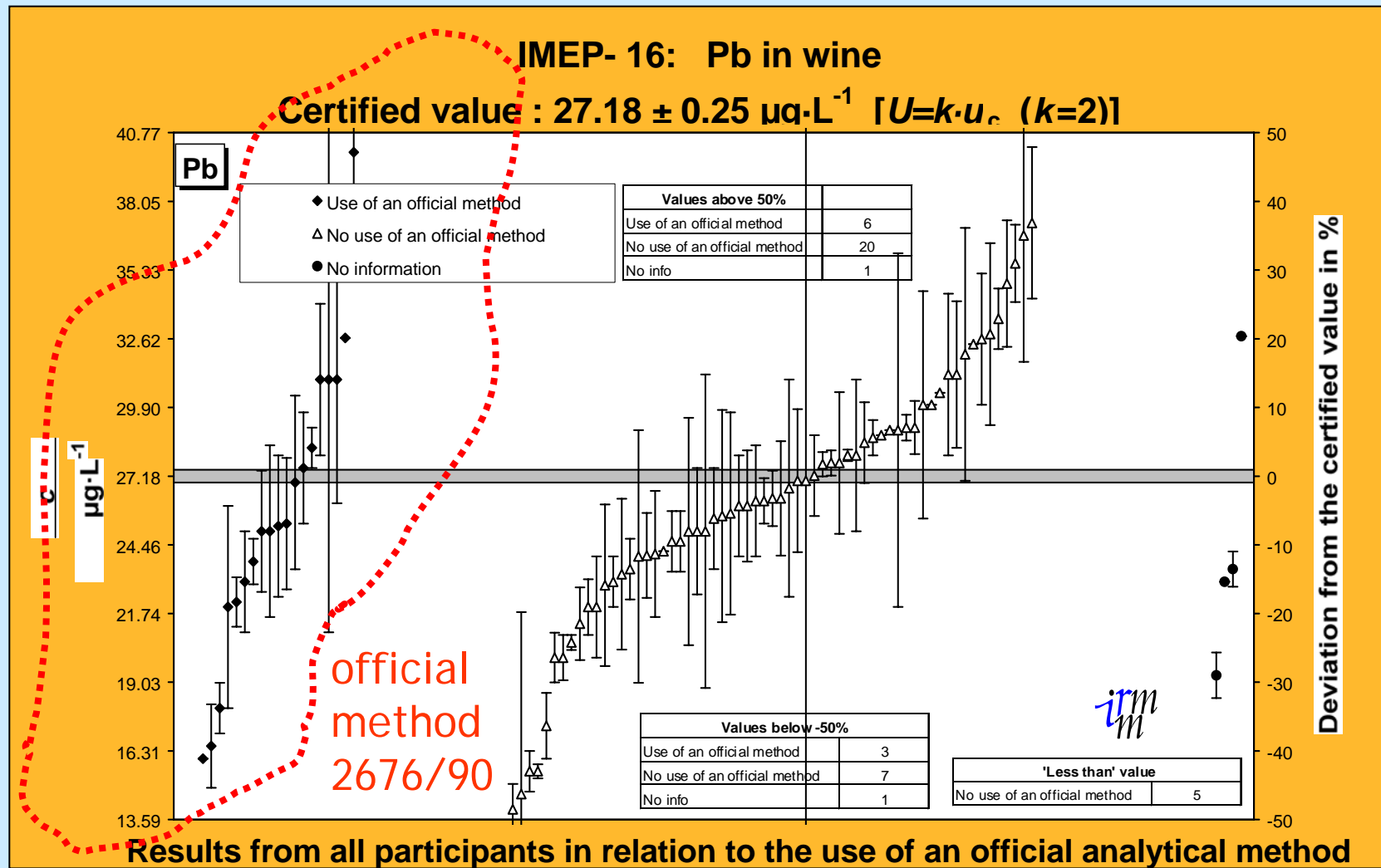
Effect on Rating	Number of Labs.	Percent
'Acceptable' >> 'Unacceptable'	17	37
'Unacceptable' >> 'Acceptable'	9	20
No change to rating	20	43

# FAPAS Areas of Potential Interest

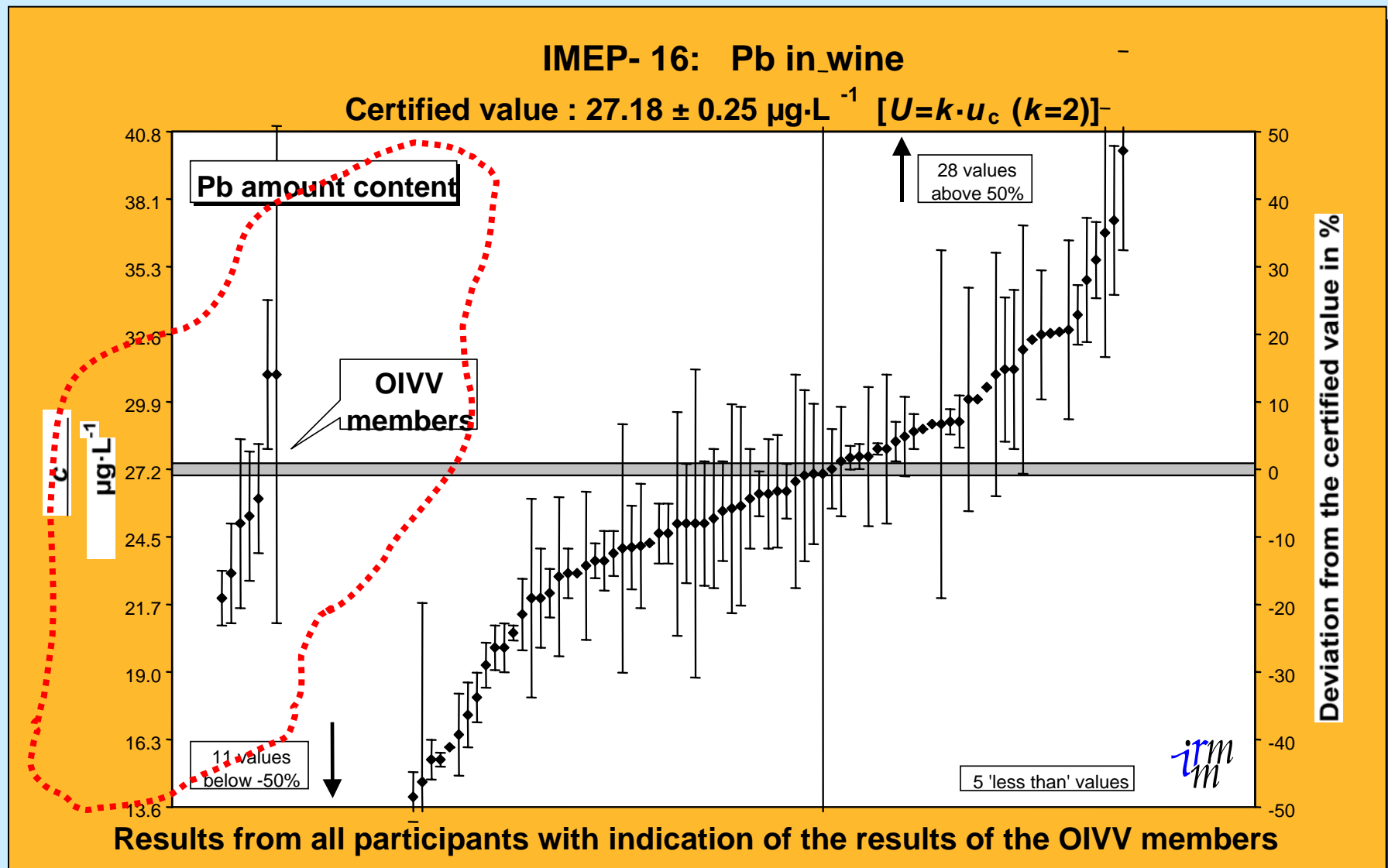


- Arsenic – bimodal results
  - Problem with sample digestion?

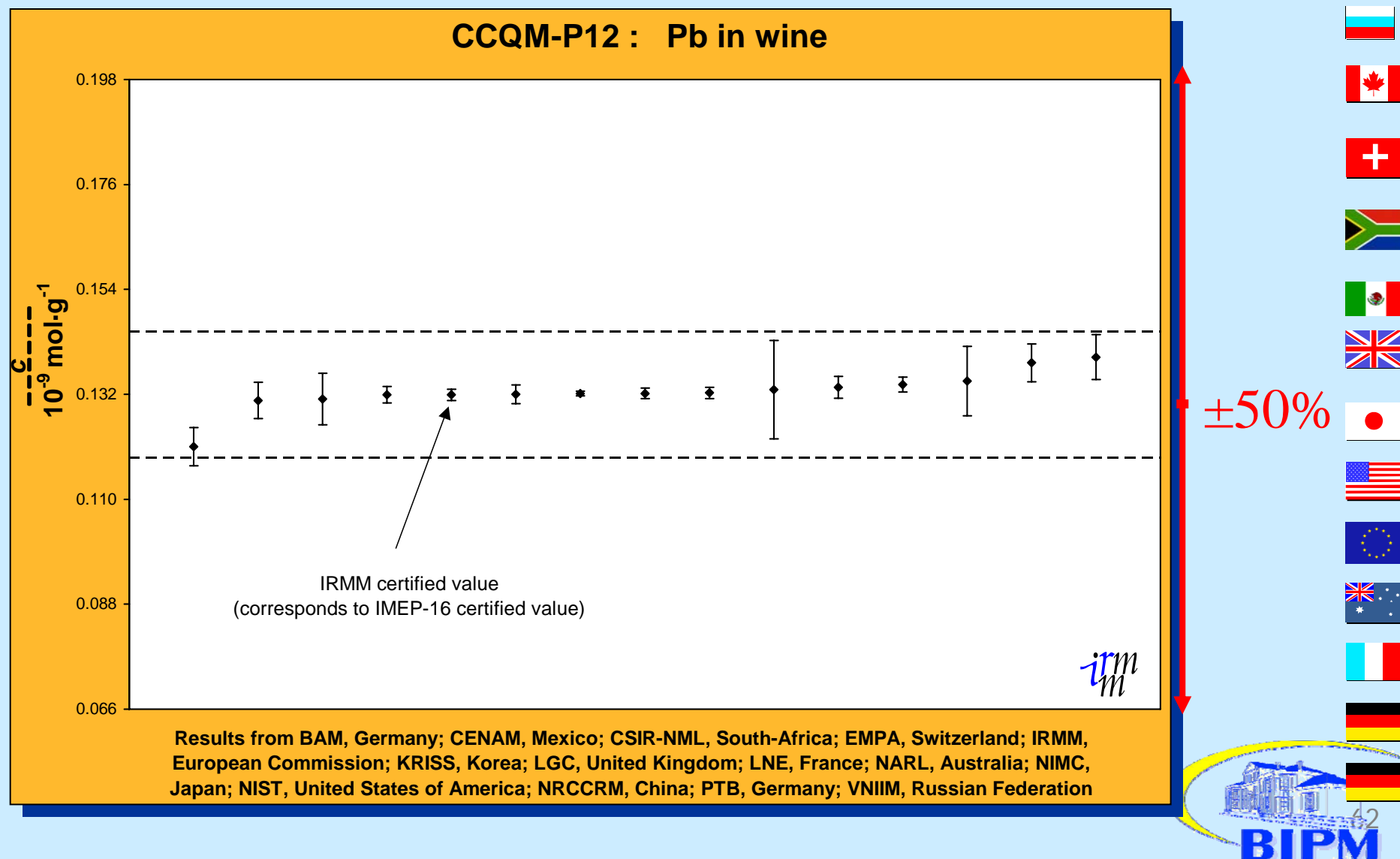
# Assessing the quality of results of measurements :



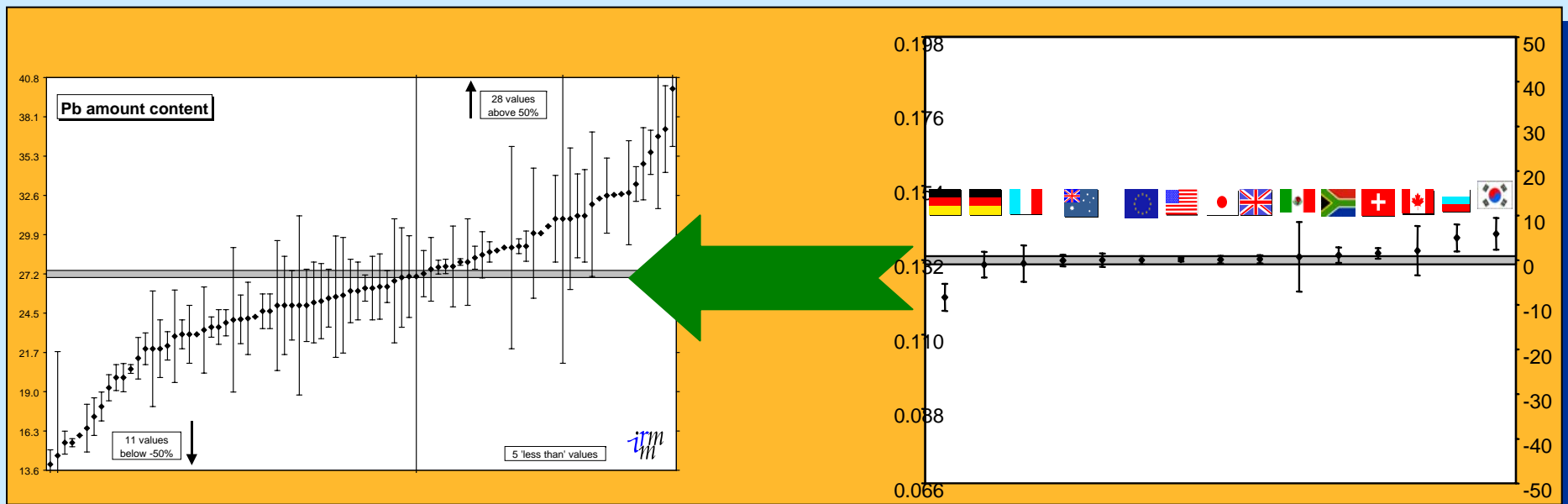
# Assessing the quality of results of measurements :



# BIPM-CCQM pilot study 12



# *OLV using a reference value, demonstrated to be equivalent at global level*



# CCQM OAWG planned activities

- Pesticide residues in fruit products (juices)
- Butyric acid in milk (marker for milk fat content; customs tariff issue)
- Growth hormones in meat
- Antibiotics and trace contaminants in fish
- Vitamins and Minerals (A, E, Folates in baby food and dietary supplements)
- Proximates in milk products (product standards)
- Dietary supplements (green tea)
- More to follow

# Areas of interest for traceable assigned values in FAPAS PT schemes

- Chloride
- Nitrite and nitrate
- Vitamins
- Low level concentrations
- Peanut protein
- Gluten
- Mycotoxins
- Butyric acid

# Where are the authorities going ?

- The EU has established a system of 4 Community Reference Laboratories (CRL's) for residue analysis, 37 National Reference Laboratories and a large number of field labs
- CRL's to assure comparability, effectiveness, quality, arbitration, advise to the EC
- Methods to comply with Minimum Required Performance Limits
- Laboratories to comply with ISO 17025
- Soon more EU reference labs

# European Reference Laboratory System

CRL  
Rome

CRL  
Bilthoven

CRL  
Fougères

CRL  
Berlin

technical and scientific support

several NRLs:

1 NRL per member state and substance/ substance group

technical and scientific support

many RFLs (approx. 32 in Germany):

Implementation of Residue Control Plan

# Conclusions (EU CRL)

Limited availability of and high demand for reliable, traceable CRM's

Consequences:

- restricted traceability, measurement uncertainty cannot be calculated
- requirements of ISO 17025 cannot be fulfilled completely
- reliability of measurement results only given to a certain degree

# Conclusions (EU CRL)

- Intensified focus on laboratory comparability (by means of PTs)
- A move to the intensified production and use of (in-house) reference materials has taken place
- However, budgetary restrictions hamper this move seriously
- A strong co-ordination and co-operation should be mandatory between CRLs and institutions dealing with the production of CRMs (DG JRC - IRMM, NMI, BIPM) to secure food safety and to prevent a waste of time and money

# Where are we going ? (1)

The workshop concluded that the CCQM/BIPM should:

- Cooperate with the IAM and the Codex Alimentarius Commission (in particular Codex Committee on Methods of Analysis and Sampling - CCMAS)
- The BIPM is now an official observer
- Support, underpin measurements in food testing, taking into account priorities indicated by the food testing sector
- Promote the application of assigned traceable reference values in PT schemes

# Where are we going ? (2)

The workshop concluded that the CCQM/BIPM should:

- Develop the activities by the relevant CCQM WGs in bio analysis (GMOs, etc.)
- Continue to establish globally recognized comparability under the CIPM MRA;
- Bring in more expert/food reference laboratories, also by designating laboratories to act as a NMI in the food testing field
- Perhaps establish a “joint committee” with the stakeholders in the food sector

# **Establishing a national network of credible, reliable, recognized dissemination of traceability in the field of classical, physical metrology**

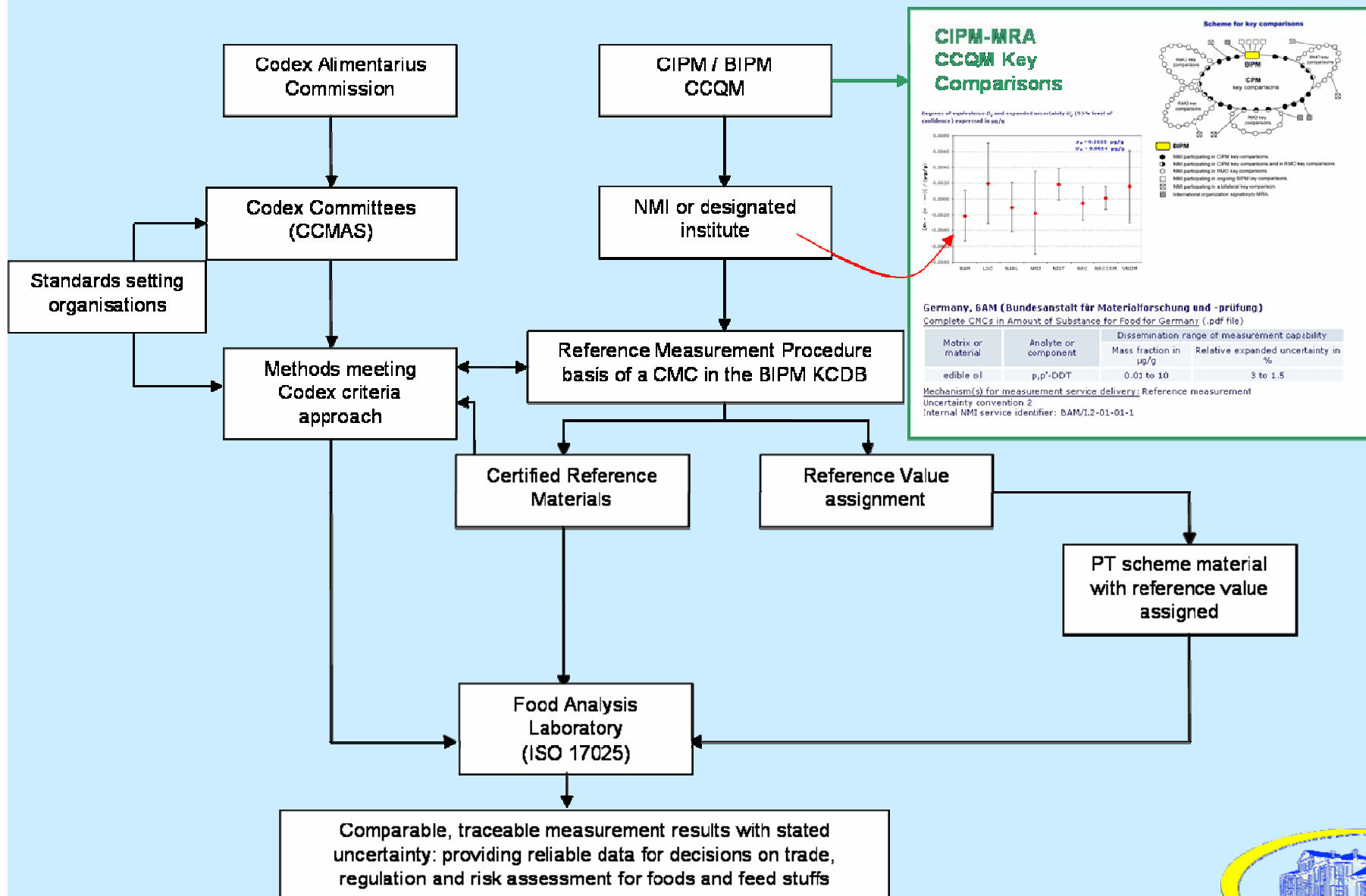
- **Top level cooperating under the Metre Convention**
  - NMI's and other designated institutes
- **Second level of accredited calibration laboratories in defined fields under the ILAC Arrangement**
  - traceable to NMI's and other designated institutes under the CIPM MRA
- **Third level of "field" laboratories**

# Establishing a national network of credible, reliable, recognized dissemination of traceability in clinical chemistry and laboratory medicine

- Top level cooperating under the Metre Convention
  - NMI's and other designated institutes
- Second level of (accredited) national reference laboratories in defined fields
  - National reference labs for clinical chemistry (nominated by responsible health care authorities)
- Third level of "field" laboratories
  - clinical chemistry and hospital laboratories
- Global cooperation under the Joint Committee for Traceability in Laboratory Medicine – JCTLM
  - CIPM/BIPM, IFCC, ILAC with broad stakeholder support

## **Establishing a regional network of credible, reliable, recognized dissemination of traceability**

- Top level cooperating under the Metre Convention
  - NMI's and other designated institutes
- Second level of (accredited) regional reference laboratories in defined fields
  - EU reference labs for food safety nominated by the EC
- Third level of (accredited) national reference laboratories in defined fields
  - national reference labs for food safety nominated by national authorities
- Fourth level of "field" laboratories
  - independent and industrial food testing labs (accredited and non-accredited)



# New areas

- Anti-doping (anabolic steroids in urine; 19-norandrosterone)
- Forensics (DNA, RNA, drugs)
- Pharmaceuticals
- Materials, commodities

# New networks

- WMO/Global Atmospheric Watch
- WHO/IFCC
- Codex Alimentarius Commission/Inter Agency Meeting
- EU Reference Laboratories
- Anti-doping Laboratories (WADA)
- International Association of Forensic Sciences(IAFS)
- Intensified co-operation with ILAC, ISO/IEC, WTO, OIML, IMEKO, IUPAC, IUPAP, etc
- Sector specific international organizations

# Conclusion

- Clear need for comparability through traceability to SI or if not yet feasible to other internationally agreed references
- Cooperation with all stakeholders needed
- Work to be done and coordinated by the different CC's under the Inter-Governmental Treaty of the "Metre Convention"
- International recognition of capabilities and competence and acceptance of results under the CIPM MRA

# Recommendation on regional level

As an example:

- Close cooperation EUROMET with:
  - ✓ EURACHEM
  - ✓ EA
  - ✓ EUROLAB
  - ✓ Sector specific laboratory organizations
  - ✓ EU regulators
  - ✓ European manufacturers associations
  - ✓ Sector specific expert/professional organizations
  - ✓ PT providers
  - ✓ CRM producers
  - ✓ CEN, a.o.

# Recommendation on national level

- Close cooperation NMI with:
  - ✓ National accreditation body
  - ✓ National standardization body
  - ✓ National laboratory associations
  - ✓ PT providers (deliver traceable reference values)
  - ✓ Regulators/ministeries/natl. sector specific regulators
  - ✓ Sector specific professional organizations
- Develop “calibration” facilities at the NMI
- Work on key pure materials (niches in the market)
- Sub-contract some work (collaborate)
- Designate sector specific expert/natl. reference labs
- Coordinate and organize workshops for stakeholders
- Cooperate internationally (SIM, CCQM) and share work

